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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,590	04/20/2000	SAMUEL J. LANDRY	07005/00302	6521

21559 7590 08/13/2003

CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/13/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/463,590

Applicant(s)

LANDRY, SAMUEL J.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8,10-13,15-19 and 58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,10-13,15-19 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicant's response filed 5/29/03 is acknowledged and has been entered.

**The following rejection remains.**

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-8, 10-13 and 15-19 stand rejected under 35 U.S.C. 102(e) as being anticipated by Hess (U.S. Patent No. 6,326,465) as evidenced by the URLs <http://us.expasy.org/cgi-bin/protp> and <http://us.expasy.org/cgi-bin/peptidecutter/peptidecutt> for the reasons of record in the Office Action mailed 2/25/03.

During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In re Prater , 162 USPQ 541, 550 - 51 (CCPA 1969).

Applicant's arguments in Applicant's response filed 5/29/03 have been fully considered but are not persuasive.

It is Applicant's position in Applicant's response filed 5/29/03 that Hess et al do not disclose modulating an immune response by employing an altered protein, fragment thereof, containing an unstable sequence inserted into a protein or fragment thereof, by artifice as required by instant claim one, i.e., the product disclosed by Hess et al is a fusion protein. It is Applicant's position that claim 1 requires an unstable polypeptide sequence be inserted by artifice *into* the naturally occurring protein, fragment thereof, into the interior of the protein, fragment thereof, and not at a terminus.

It is the Examiner's position that the claim language recited in instant claim 1, i.e., into, as broadly interpreted is not limited to insertion into the interior of a linear sequence, i.e., that the insertion can be at any portion of the protein, fragment thereof.

**The following is a new ground of rejection**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to practice the method for stimulating an immune response toward naturally-occurring HIV gp120 protein in a human comprising administering to a human an altered HIV gp120 protein, wherein a human HSP 10 mobile loop has been inserted by artifice into said altered HIV gp120 protein. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the claim encompasses methods of inducing an immune response where no immune response will occur or the said immune response will be ineffective.

The specification does not disclose the claimed method in vivo in any animal or human.

Evidentiary reference Haynes et al (Lancet 1996 348, 933-937, IDS reference) teaches that HIV exhibits extraordinary variability, and the rapidity and extent of HIV mutation and the half-life of HIV variants is about 2 days, and that there is a lack of an exact animal model of HIV-induced AIDS and a lack of understanding of the correlates of positive immunity to HIV. Haynes et al further teach that current HIV vaccines containing HIV gp120 envelope have been tested in humans, but they have had a major limitation of neutralizing only T-cell tropic laboratory-adapted HIV strains grown in T cell lines, but not neutralizing HIV primary isolates, i.e., does not stimulate an immune response toward a naturally occurring HIV gp120 protein in a human as recited in instant claim 58.

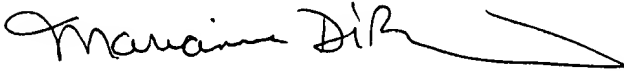
There is insufficient guidance in the specification as to how to practice the method of the instant invention. There is no disclosure in the specification as to administering in vivo in a human or any animal said altered HIV gp120 protein. Undue experimentation would be required of one skilled in the art to practice the instant invention. See In re Wands 8 USPQ2d 1400 (CAFC 1988).

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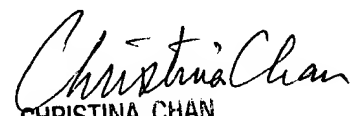
5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061. The Examiner can normally be reached on Monday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 (before final) or 703-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Marianne DiBrino, Ph.D.  
Patent Examiner  
Group 1640  
Technology Center 1600  
August 11, 2003



CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600